

Declaration of Boles

Exhibit A

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE**

**PLANNED PARENTHOOD OF)
TENNESSEE AND NORTH)
MISSISSIPPI, MEMPHIS CENTER FOR)
REPRODUCTIVE HEALTH,)
KNOXVILLE CENTER FOR)
REPRODUCTIVE HEALTH,)
FEMHEALTH USA, INC., d/b/a)
CARAFEM, and AUDREY LANCE,)**

Plaintiffs,)

v.)

**Case No. 3:20-cv-00740
Judge Campbell**

**HERBERT H. SLATERY III, Attorney)
General of Tennessee, in his official)
capacity; LISA PIERCEY, M.D.,)
Commissioner of the Tennessee)
Department of Health, in her official)
capacity; RENE SAUNDERS,)
M.D., Chair of the Board for Licensing)
Health Care Facilities, in her official)
capacity; W. REEVES JOHNSON, JR.,)
M.D., President of the Tennessee Board)
of Medical Examiners, in his official)
capacity; HONORABLE AMY P.)
WEIRICH, District Attorney General)
of Shelby County, Tennessee, in her)
official capacity; GLENN FUNK, District)
Attorney General of Davidson County,)
Tennessee, in his official capacity;)
CHARME P. ALLEN, District Attorney)
General of Knox County, Tennessee, in her)
official capacity; and TOM P.)
THOMPSON, JR., District Attorney)
General for Wilson County, Tennessee, in)
his official capacity,)**

Defendants.)

DECLARATION OF DR. BRENT BOLES

I, Brent Boles, M.D., pursuant to the provisions of 28 U.S.C. § 1746, do hereby declare as follows:

1. I am Brent Boles, a practicing obstetrician and gynecologist in Murfreesboro, Tennessee.
2. I have been board certified for more than twenty years and have been in practice in Murfreesboro for the last fifteen years. I teach at the University of Tennessee School of Medicine and the Meharry College of Medicine. I also am a member of the Medical Advisory Board for both Heartbeat International and Abortion Pill Reversal (or Rescue). (“APR”). I have attached my curriculum vitae as *Exhibit 1*.
3. On March 10, 2020, I testified before the Tennessee General Assembly, specifically the House Health Committee, on HB 2568 (the provisions of which were subsequently enacted as part of HB2263/SB2196). At that hearing, an amendment was offered to the bill that would require abortion providers to inform a patient seeking a medication abortion that, if the patient changes her mind after taking the first pill, she may be able to avoid, cease, or reverse the effects of that first pill in the two step abortion pill series, particularly if she seeks assistance fast enough. I testified about the need to provide women with this information that there is a medical regime that is both safe and potentially effective in reversing the effect of the first pill. Attached as *Exhibit 2* is a true and correct transcription by a court reporter of my testimony as part of this bill’s Legislative History. (*See* Ex. 2, p. 4, l. 16—p. 45, l. 25).
4. The abortion pill medication treatment involves two pills: Mifeprex or mifeprestone or RU486 (it goes by three different terms), and Cytotec or misoprostol. (*See generally* Ex. 2, p. 5, l. 10—p. 6, l. 1).

5. The first pill, mifepristone, is a progesterone blocker. Progesterone is a hormone that is vital to the success of a pregnancy throughout the course of a pregnancy. When the action of progesterone is interfered with in the first trimester by Mifepristone, the drug may cause loss of the embryo or the fetal life, and in some cases expulsion of the pregnancy tissue.
6. Mifepristone alone is not always effective in ending a pregnancy. A study of data published by Dr. Daniel Grossman (an abortion provider) found that as few as 8% of pregnancies survived when only mifepristone was administered. (*See* Ex. 2, p. 22, l. 19—p. 23, l. 13).
7. The second pill, Cytotec, ensures that the tissue is expelled and is given twenty-four to forty-eight hours after the first pill.
8. When a patient has changed her mind and has taken the mifepristone but has not yet taken the Cytotec, administering natural progesterone may result in preventing loss of the fetal life in as many as sixty-eight percent (68%) of pregnancies. (*See* Ex. 2, p. 5, l. 10—p. 6, l. 13). The administration of natural progesterone has not been shown to have any increase in birth defects or in adverse effects for women – and is safer than taking the mifepristone and simply choosing to not take the Cytotec. (*See generally* Ex. 2, p. 6, l. 14—p. 7, l. 19).
9. As part of the Abortion Pill Reversal network, I am on call to help advise and assist mothers who take the first abortion pill, change their mind, want to try to save their baby, and find the network (typically through their own searching). (*See generally* Ex. 2, p. 27, l. 4—p. 28, l. 5).
10. I do not keep a list, but I would estimate that I have prescribed natural progesterone to more than 20 women who wanted to reverse their abortion processes – some right here in Tennessee who then had healthy babies. The Abortion Pill Reversal network has tracked more than 1,000 living, healthy babies with no increased risk of birth defects who have

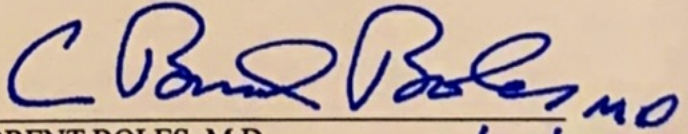
been delivered because patients interacted with the APR network. (*See* Ex. 2, p. 13, l. 16—p. 15, l. 10; p. 44, l. 14—p. 45, l. 17).

11. I have even delivered some of those babies myself and have seen firsthand how the abortion pill process can be reversed in some situations.
12. Published studies, such as in 2007, 2012, and 2018, support the efficacy of this progesterone treatment.¹ (*See* Ex. 2, p. 7, l. 6-19; p. 22, l. 19—p. 23, l. 13; p. 30, l. 15—p. 31, l. 22). The largest case study in 2018 included 754 patients. Those who took the currently recommended progesterone regimen had a 68% success rate in reversing the abortion process—with no increased outcomes that were unfavorable for the mother or for the baby.
13. This method of progesterone treatment has not been shown to cause any increase in adverse effects for the women who choose to pursue the treatment.
14. Further, this method of progesterone treatment has not been shown to cause any increase in birth defects for the fetuses of the women who choose to pursue the treatment.
15. A study released by the American College of Obstetrics and Gynecology, which was authored by Dr. Creinin (an abortion physician), unsuccessfully attempts to support a claim, based upon only a series of 12 patients, that attempting to reverse the abortion process is neither safe nor effective. Analysis of the three patients who experienced bleeding issues (out of the twelve total patients) showed that two of those who took mifepristone and a placebo needed hospital treatment, while the one who received progesterone treatment, upon arriving at the hospital, was found to not need surgical

¹ *See* Delgado G, Davenport M. Progesterone use to reverse the effects of mifepristone. *Annals of Pharmacotherapy*. 46 2012 Dec;46(12):e36.; Delgado G, et al. A case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone. *Issues in Law and Medicine* (2018) 33(1): 21- 31.

- intervention or a blood transfusion for the deceased embryo she spontaneously passed. (See Ex. 2, p. 8, l. 1—p. 10, l. 2; p. 11, l. 3—p. 13, l. 12; p. 15, l. 23—p. 17, l. 10; p. 42, l. 2—22).
16. The American Medical Association's Code of Ethics in sections 1.1.1 and 1.1.3 require the physician treating the patient to give an accurate and complete disclosure of information in the informed consent process and to do so in a manner that it is not self-serving to the physician's own interests. (See Ex. 2, p. 10, l. 1—12).
17. With a success rate that may be as high as 68%, women need to be told of the possibility that progesterone treatment may assist in reversing their abortion process after taking the mifepristone if they so choose. To not inform them of this possibility is to not give them a full and complete disclosure in the informed consent process (and particularly if the women inquires after taking the first pill) and is a violation of both sections of the AMA's Code of Ethics. (See Ex. 2, p. 23, l. 14—23).
18. Tennessee's recently passed abortion law (HB2263/SB2196) is an important step in ensuring that mothers receive complete and accurate information that the abortion process "may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone" (emphasis added).

I declare under penalty of perjury that the foregoing is true and correct. Executed by me on the ____th day of September, 2020, in Murfreesboro, Tennessee.


C. BRENT BOLES, M.D. 9/14/2020

Curriculum Vitae of Boles

Attachment 1

C. Brent Boles, M.D.
Covenant Healthcare for Women, P.L.L.C.

1800 Medical Center Parkway
Suite 325
Murfreesboro, Tennessee 37129
615-867-0034

Professional History

- Physician and Owner, Covenant Healthcare for Women, P.L.L.C., January, 2006 to present
- Medical Director of Portico (local crisis pregnancy center) 2008 to present
- Vice Chief of Obstetrics and Gynecology, Middle Tennessee Medical Center, Murfreesboro TN, 2007-2008
- Chief of Obstetrics and Gynecology, Middle Tennessee Medical Center, Murfreesboro TN, 2009-2010
- Associate Clinical Professor in the University of Tennessee Department of Emergency Medicine at Saint Thomas Rutherford Hospital, July 2015 to present
- Associate Clinical Professor and Assistant Residency Director for the Saint Thomas Rutherford Campus, Department of Obstetrics and Gynecology, Meharry College of Medicine, 2006 to present
- Clinical Instructor for the University of Tennessee Physician Assistant School, 2016 to present
- IC Research, Principal Investigator, 2018 to present
- OB/GYN Associates, July 2005-December 2005
- Murray Woman's Clinic, July 1996-June 2005
- Middle Tennessee Medical Center Laborist Program Director, November 2006-March 2011
- Certified on the Da Vinci Xi robotic surgery platform
- Member of the Medical Advisory Board for Heartbeat International
- Member of the Medical Advisory Board for Abortion Pill Reversal

Educational History

- Certified by the American Board of Obstetrics and Gynecology, November 1998 to present
- Chief Administrative Resident, University of Louisville School of Medicine, Department of Obstetrics and Gynecology, July 1995 - June 1996
- Internship and Residency, University of Louisville School of Medicine, Department of Obstetrics and Gynecology, July 1992-June 1996
- Doctor of Medicine, University of Louisville School of Medicine, August 1988-May 1992
- Bachelor of Science in Biology, Murray State University, August 1984-May 1988

Licensure

- Tennessee Board of Medical Examiners, 2004 to present
- Kentucky Board of Medical Licensure, 1993 to 2011
- Drug Enforcement Agency Registration, 1993 to present

Memberships

- American Institute of Ultrasound in Medicine, 1998 to 2005
- International Society for Clinical Densitometry, 1998 to 2005
- Christian Medical and Dental Association
- American Association of Pro-Life Obstetricians and Gynecologists

Awards

- Professor of the Year Award, University of Tennessee Health Science Center, Saint Thomas Rutherford Department of Emergency Medicine, 2016
- Meharry Appreciation Award, 2009
- Foundation Award for Clinical Excellence, Department of Obstetrics and Gynecology, University of Louisville School of Medicine, 1994
- Best Clinical Teacher Awards, University of Louisville School of Medicine, 1993, 1994, 1996

- Clinical Research Awards, University of Louisville School of Medicine, Department of Obstetrics and Gynecology, 1995 and 1996
- Laparoscopic Skills Award, University of Louisville School of Medicine, Department of Obstetrics and Gynecology, 1995
- Presidential Scholarship Award, Murray State University, 1984 to 1988

House Health Committee HB2568

Attachment 2

AUDIO RECORDING

March 10, 2020



VETERAN COURT REPORTING
D. Rochelle Koenes, RPR, LCR
veterancourtreporting@gmail.com
(931) 919-8932

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12 AUDIO RECORDING

13 of

14 HOUSE BILL 2568

15 dated

16 March 10, 2020

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23 Veteran Court Reporting
veterancourtreporting@gmail.com
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P R O C E E D I N G S

(WHEREUPON, the following is
transcribed from an audio recording as follows:)

IN THE HOUSE HEALTH COMMITTEE
March 10, 2020

(WHEREUPON, On the above date, there
came up for consideration in the House Health
Committee of the Tennessee House, House Bill 2568,
sponsored by Representative Faison, and discussion
pertaining to this bill was as follows:)

MR. CHAIRMAN: And with that we have a
pretty extensive calendar today, and I would like to
get us to Item Number 1, House Bill 2568 by --
Representative Faison you are recognized.

REPRESENTATIVE FAISON: Good morning,
Committee, Mr. Chairman.

MR. CHAIRMAN: Do you have a motion?

UNIDENTIFIED SPEAKER: Second.

REPRESENTATIVE FAISON: Committee, House
Bill 2568 is a bill that I brought in the attempt
for if a young lady has decided to go get an
abortion, and it's the abortion where they give a

1 pill -- they typically give two pills -- one you
2 take at the clinic and one 48 hours later that you
3 take. If they have -- for whatever reason, they
4 change their mind, I want them to know that there's
5 a possibility that they can get that reversed and
6 this bill would have an -- abortion clinic providers
7 put up a posting that there is a possibility that
8 you can reverse it and also let them know if they
9 change their mind that they can reverse it.

10 MR. CHAIRMAN: You have an amendment on
11 the bill?

12 REPRESENTATIVE FAISON: I do, yes, sir.
13 And the Amendment Drafting Code is 0148 -- -14982.

14 MR. CHAIRMAN: Drafting Code 014982. I
15 have a motion and a second.

16 Okay. The amendment is properly before
17 us. Can you give us comments on the amendment?

18 REPRESENTATIVE FAISON: Just exactly
19 what I just said.

20 MR. CHAIRMAN: Do we have questions from
21 the committee on the amendment? If not, we do have
22 somebody -- we were supposed to have two people here
23 to testify on this -- on the amendment. We can
24 either take questions now or we can go out of
25 session.

1 I think only one person has shown up to
2 testify. But do we have any questions before we go
3 out of session?

4 Representative Clemmons, do you have a
5 question?

6 REPRESENTATIVE CLEMMONS: I was just
7 going to recommend that we go out of session first
8 and then defer questions until after that.

9 MR. CHAIRMAN: All right. Seeing none,
10 without objection, we will go out of session.

11 Our first -- I believe, maybe, the only
12 person that we have here that may testify,
13 Dr. Brent Boles, if you can come up and please make
14 sure the mic is on. Tell us who you are and who
15 you're with.

16 DR. BOLES: Good morning. My name is
17 Brent Boles. I am an OB/GYN who's been board
18 certified for more than 20 years and has been in
19 practice in Murfreesboro for the last 15 years. In
20 addition to my private practice and academic
21 teaching appointments that I have with both the
22 University of Tennessee School of Medicine and the
23 Meharry College of Medicine, I am a member of the
24 medical advisory board for both Heartbeat
25 International and Abortion Pill Reversal.

1 I'm here this morning to speak in
2 support of the representative's bill that would
3 require abortion providers to simply notify a
4 patient during the informed consent process that if
5 they choose to change their mind after they have
6 taken the first pill, that there is a medical
7 regimen that is both safe and effective that has
8 the potential to reverse the effects of the first
9 pill in the abortion pill series.

10 The history of abortion pill medication
11 treatment is that in the year 2000 the Food and
12 Drug Administration approved a drug produced by a
13 pharmaceutical company called Danco. That drug is
14 known as Mifeprex for mifepristone or RU486. There
15 are three different terms by which it is called.

16 This pill is a progesterone blocker.
17 Progesterone is a hormone that is vital to the
18 success of a pregnancy throughout the course of the
19 pregnancy. And when the action of progesterone is
20 interfered with in the first trimester, the
21 mifepristone will cause loss of the embryo or the
22 fetal life. And then in some cases, cause
23 expulsion of the pregnancy tissue. In order to
24 ensure that the tissue is expelled, a second
25 medication called Cytotec is given 24 to 48 hours

1 after the first pill is dosed.

2 Basic principals of pharmacology have
3 led us to discover that when a patient has changed
4 her mind and has taken the mifepristone but has not
5 yet taken the Cytotec, that if you simply
6 administer natural progesterone, you have as high
7 as a 68 percent success rate in preventing loss of
8 the fetal life.

9 This method of treatment has not been
10 shown to cause any increase in adverse effects for
11 the women who choose to pursue this. In fact, it
12 is more safe than taking the mifepristone and
13 simply not using the Cytotec.

14 This was discovered first in 2007 by a
15 physician named Matthew Harrison in South Carolina
16 who was approached by a patient who had taken the
17 mifepristone and desired to change her mind. He
18 studied the pharmacology of the drug and gave her a
19 prescription of progesterone and she later
20 delivered a living baby at term. At the same time,
21 Dr. George Delgado on the west coast was approached
22 with a similar problem by a similar patient and
23 found similar results.

24 The first case series that was
25 published that reported on this was released in

1 2012. It was a small case series and that is the
2 criticism that the abortion industry has of this
3 process. They claim that such a small case series
4 with only six patients cannot be used to draw any
5 conclusions.

6 The truth of the matter is that case
7 series showed a two out of three success rate of
8 the six patients who pursued reversal. Four
9 delivered living babies later in their pregnancy.
10 That is not the only study, but the abortion
11 industry would like for you to believe that it was.
12 There have since been at least three other
13 published studies, the largest one of which
14 included 754 patients in whom the current
15 recommended regimen had a 68 percent success rate
16 at reversing the abortion process with no increased
17 outcomes that were unfavorable for the mother or
18 the baby. There were no birth defects. There were
19 no other issues reported in that study.

20 Another study is about to begin, and I
21 will be one of the principal investigators in this
22 study that will compare methods of administering
23 the progesterone. So there's ongoing research that
24 I believe will continue to demonstrate both the
25 efficacy and the safety of this medication.

1 The recent study that was released by
2 the American College of Obstetrics and Gynecology
3 authored by Dr. Creinin, who is an abortion
4 physician, makes the claim, based on a series of
5 only 12 patients, that attempting to reverse
6 abortion is neither safe nor effective.

7 I find it interesting that the abortion
8 industry's criticism of the Delgado case series in
9 2012 focused on the fact that it only had a small
10 number of patients and you can't draw conclusions
11 from that, but now they expect us to draw
12 conclusions from a study that also has a small
13 number of patients, namely only 12. They claim
14 from this study that it is -- that you -- it is not
15 safe for the patient to take the mifepristone and
16 then not complete the process with the Cytotec.

17 They make this conclusion because three
18 of the twelve patients in that study had to go to
19 the emergency room for bleeding. The truth of the
20 matter when you break down those numbers, there
21 were six patients in the study who took
22 mifepristone and placebo, meaning they were not
23 being treated for attempted reversal, the other six
24 patients took mifepristone and progesterone in the
25 current recommended regimen.

1 Of the six patients who took
2 progesterone, five of them had ongoing pregnancies.
3 So the success rate was five out of six, more than
4 80 percent. One of those patients was taken to the
5 emergency room because she was worried about the
6 amount of bleeding that she had. But when she
7 arrived at the emergency, her embryo was no longer
8 living and she spontaneously passed the tissue
9 without requiring a DNC or any other surgical
10 intervention and without requiring a blood
11 transfusion. The other two patients who required
12 treatment in the emergency room, both were taken to
13 the emergency room because of heavy bleeding. Both
14 required surgical aspiration of the pregnancy
15 tissue, and one of the two required a transfusion.

16 So the real conclusion that you can
17 draw from the Creinin study is that it is not safe
18 to take mifepristone and then decide not to take
19 the Cytotec. So when a patient changes her mind,
20 if she can't get help and can't figure out how to
21 reverse the process and decides not to take the
22 Cytotec, then that is dangerous for her. But the
23 other conclusion is that when she takes the -- when
24 she is made aware of the reversal regimen and takes
25 it, it is not only safe but it is effective at a

1 minimum 68 percent of the time and perhaps as much
2 as more than 80 percent of the time.

3 The American Medical Associations Code
4 of Ethics in sections 1.1.1 and 1.1.3 require the
5 physician treating the patient to give a full,
6 accurate, and complete disclosure of information in
7 the informed consent process and do so in a way
8 that is not self-serving the patient's own
9 interest -- or the physician's own interest.

10 Refusing to tell patients that a reversal regimen
11 is possible is a violation of both sections of the
12 AMA code of ethics.

13 MR. CHAIRMAN: Thank you for that
14 testimony.

15 Do we have questions while we are --
16 Representative Dixie, you are
17 recognized.

18 REPRESENTATIVE DIXIE: Thank you,
19 Mr. Chairman. I just have a couple of quick
20 questions.

21 You gave us a lot of stats about
22 studies. Obviously, most studies say that they are
23 extensive and hundreds, if not thousands of
24 patients.

25 Why was this study stopped at six

1 patients?

2 DR. BOLES: Which study?

3 REPRESENTATIVE DIXIE: Well, you said
4 earlier that there was a study that had six patients
5 that went through and they took both and then the
6 other one had the placebos. Why was it only stopped
7 at twelve people?

8 DR. BOLES: You're referring to the
9 Creinin study, which had six patients in each arm.
10 There were twelve patients in the study. Their
11 initial plan was to enroll 40. It is typical when
12 you're conducting a study and you see what you
13 believe are adverse outcomes to stop the study early
14 if there are indications that it is dangerous to the
15 patient. The stated reason for stopping the study
16 was that three patients had to -- three out of
17 twelve had to be taken to the emergency room for
18 bleeding.

19 REPRESENTATIVE DIXIE: Really, three out
20 of six because six only had placebos.

21 DR. BOLES: There were twelve patients
22 total. One of the patients who went to the ER for
23 bleeding came from the progesterone group and two of
24 them came from the placebo group. So the study at
25 that point had twelve patients enrolled with a plan

1 to enroll 40. But they stopped because three of the
2 twelve were evaluated for bleeding.

3 REPRESENTATIVE DIXIE: I want to circle
4 back to make sure I got your answer correct.

5 DR. BOLES: Okay.

6 REPRESENTATIVE DIXIE: You said that it
7 was stopped because they thought it would have
8 adverse effects going forward.

9 DR. BOLES: Yes. They stopped the study
10 because three of the twelve patients had to be
11 evaluated for bleeding. When you evaluate which
12 patients had to be evaluated for bleeding, only one
13 was from the progesterone group. And she did not
14 need a blood transfusion and she did not need
15 surgery. The patients who had to have
16 interventions -- surgery and/or a blood
17 transfusion -- came from the group that took the
18 Mifeprex but did not take the progesterone to
19 attempt to reverse.

20 REPRESENTATIVE DIXIE: So based on the
21 study that you quoted that you gave us right here,
22 this doesn't sound like it's safe and effective if
23 it was stopped for adverse reasons.

24 DR. BOLES: It was stopped because two
25 of the patients who did not take the treatment had

1 to have a blood transfusion or surgery. Those were
2 patients that were not in the treatment arm. They
3 were in the placebo arm. And the reason for
4 stopping the study -- if you want to know what I
5 believe that you can conclude based on that is they
6 didn't like the data. The adverse outcomes that
7 required intervention were in the group that did not
8 get the reversal treatment. And the reversal
9 treatment, which they claim is not effective in
10 their six patients was shown to be more than 80
11 percent effective. I believe that's why the study
12 was stopped.

13 MR. CHAIRMAN: Representative Dixie?

14 REPRESENTATIVE DIXIE: One last
15 question.

16 You did mention that there were babies
17 delivered after this. Has there been any studies
18 or any follow up on how the babies are doing
19 emotionally, physically? Any kind of side effects
20 since then?

21 MR. CHAIRMAN: Dr. Boles, you're
22 recognized.

23 DR. BOLES: The abortion pill reversal
24 mechanism involves a -- there's a website that
25 patients go to. Abortion providers don't tell

1 patients about the availability of this regimen.
2 The people who find it go to their smart phone or
3 their iPad and they go to Google and they say, "Can
4 an abortion pill be reversed?" The thing that pops
5 up is abortionpillreversal.com, which is a free,
6 nonprofit service that is provided to patients with
7 a toll-free 24-hour-a-day hotline.

8 Through that hotline, the patients who
9 are truly interested in pursuing reversal are
10 connected with one of over 500 physician providers
11 across the country who will prescribe this regimen
12 for them. I'm one of those providers. The
13 statistics on the outcomes of the patients who use
14 that mechanism has been tracked and there are
15 currently more than a thousand living, healthy
16 babies with no increased risk of birth defects who
17 have been delivered because patients have
18 interacted with the abortion pill reversal hotline.

19 In fact, one other positive thing,
20 other than saving the life of the baby, the
21 progesterone supplementation early in the pregnancy
22 according to our statistics of more than a thousand
23 deliveries accomplished are that, when you look at
24 the preterm delivery rates of those babies, the
25 general preterm delivery rate in the United States

1 is about 10 percent. And for patients who use the
2 abortion pill reversal regimen and are successful,
3 the preterm delivery rate is under 3 percent.

4 So not only are there no increase in
5 birth defects and no increase in bad maternal
6 outcomes, there is a decrease in the risk of
7 preterm delivery, which is one of the biggest
8 problems in children's health care in the country
9 and the number one cause of cerebral palsy in
10 America.

11 MR. CHAIRMAN: Representative Dixie?

12 REPRESENTATIVE DIXIE: I promise this is
13 my last question.

14 DR. BOLES: It's okay.

15 REPRESENTATIVE DIXIE: Currently, are
16 there any laws right now that prohibit you from
17 doing what you're doing now as far as giving these
18 two pills for this procedure?

19 DR. BOLES: No.

20 REPRESENTATIVE DIXIE: There's no --
21 okay. That's my last question.

22 Thank you. Thank you, Mr. Chairman.

23 MR. CHAIRMAN: Thank you.

24 To clarify on his point on this, the
25 study that had the six patients that got a placebo

1 and six patients that got progesterone as the
2 second pill, did they -- if they gave Cytotec, that
3 was not part of those 12 patients; is that correct?

4 DR. BOLES: That's correct. It was not.

5 MR. CHAIRMAN: And so what you can take
6 from that study would be that, if a patient was not
7 adequately informed and they were not compliant with
8 their second pill that a portion of those may end up
9 in the ER but a significant portion would -- could
10 carry the baby to term and even a more significant
11 portion of those if the reversal pill was given
12 could carry that to term; is that correct?

13 DR. BOLES: Could you say that again? I
14 want to be sure I got it clearly.

15 MR. CHAIRMAN: Okay. So let's separate
16 them into three groups. The first group is they get
17 the abort- -- the first pill, mifepristone.

18 DR. BOLES: Yes.

19 MR. CHAIRMAN: And then they are
20 compliant with the Cytotec then they would abort?

21 DR. BOLES: Yes.

22 MR. CHAIRMAN: If they were not
23 compliant, that would be the equivalent of the
24 placebo group and a significant portion of those
25 could carry to term. But based on that minor study,

1 a portion of those may end up in the ER and those
2 are the ones that got the blood transfusions and had
3 to have the evacuation.

4 DR. BOLES: That is correct.

5 MR. CHAIRMAN: But if the patient was
6 informed that if they came back and had the reversal
7 pill, still, a small percentage may miscarry at that
8 point in time but a significant portion of those
9 would carry to term?

10 DR. BOLES: That's correct.

11 MR. CHAIRMAN: All right. Thank you.

12 Representative Clemmons, you're
13 recognized.

14 REPRESENTATIVE CLEMMONS: Thank you, Mr.
15 Chairman.

16 And thank you for being here today.

17 DR. BOLES: Thank you.

18 REPRESENTATIVE CLEMMONS: I just want to
19 get some background.

20 You're an OB/GYN, you say?

21 DR. BOLES: Yes.

22 REPRESENTATIVE CLEMMONS: And how many
23 years have you been in practice?

24 DR. BOLES: I graduated from medical
25 school in 1992; so 28 years as a physician. The

1 first four of those were my residency; so 24 years
2 in independent practice.

3 REPRESENTATIVE CLEMMONS: And during
4 that time frame, about how many abortions have you
5 performed?

6 DR. BOLES: None.

7 REPRESENTATIVE CLEMMONS: And are you
8 not trained to do those or is that a --

9 DR. BOLES: I chose not to participate
10 in the abortion training.

11 REPRESENTATIVE CLEMMONS: And this --
12 these pills that we are discussing here, are they
13 FDA approved?

14 DR. BOLES: They are FDA approved, yes.

15 REPRESENTATIVE CLEMMONS: And how long
16 have they been FDA approved?

17 DR. BOLES: Since 2000.

18 REPRESENTATIVE CLEMMONS: Since 2000?

19 DR. BOLES: Yes.

20 REPRESENTATIVE CLEMMONS: So you
21 discussed the clinical trials in 2012, what were the
22 trials before that were approved by the FDA?

23 MR. CHAIRMAN: Dr. Boles, you're
24 recognized.

25 DR. BOLES: The FDA trial that was

1 conducted by Danco, the pharmaceutical company, was
2 the first trial and that resulted in the FDA
3 approval. To my knowledge, there have been no
4 further FDA sanctioned trials. The FDA did in the
5 last few years based on data submitted by Danco
6 broadened the indication for which mifepristone can
7 be given. In 2000, they approved it for up to seven
8 weeks and then a few years ago they broadened that
9 to ten weeks. But that was not based upon any other
10 brand new randomized trial.

11 The other trials which I discussed, the
12 studies which were case series reports and other
13 studies, were not conducted by the Food and Drug
14 Administration or by Danco Pharmaceuticals. They
15 were conducted by the people who have developed the
16 reversal regimen.

17 REPRESENTATIVE CLEMMONS: So with the
18 reversal regimen itself, is that process -- I'm
19 trying to get my head around the peer review depth
20 or the depth of peer review on the reversal process
21 itself as opposed to the separate pills.

22 DR. BOLES: The first study, the limited
23 case series of only six patients that was published
24 in 2012, was published in a peer review journal
25 called The Annals of Pharmacotherapy. The largest

1 series of 754 patients who were evaluated in a more
2 structured manner was published in a peer review
3 journal called Issues in Law and Medicine.

4 REPRESENTATIVE CLEMMONS: Where was
5 that?

6 DR. BOLES: Issues in Law and Medicine.

7 REPRESENTATIVE CLEMMONS: That's the
8 actual group?

9 DR. BOLES: That's the name of the
10 journal.

11 REPRESENTATIVE CLEMMONS: So the pills
12 themselves have been approved, but is the process
13 itself and the rate of success of the reversal, is
14 that approved in any way by the FDA, or is it just
15 standalone?

16 MR. CHAIRMAN: Dr. Boles, you are
17 recognized.

18 DR. BOLES: The Food and Drug
19 Administration does not require that prescription
20 medications be used only for their FDA approved
21 indications. Most prescriptions that you take may
22 be given for what are considered off-label
23 indications. Once a medication has been proven to
24 be safe and effective for the condition for which it
25 was originally approved, it can be used for any

1 other purpose for which it was approved or for which
2 it has been shown to be effective.

3 Progesterone itself, natural
4 progesterone has been used in women's health for
5 over 50 years. If there are women in this room
6 that are on a birth control method that's
7 prescribed that is anything other than a copper
8 IUD, they have a form of prescription progesterone
9 in their system right now. Menopausal women
10 receive progesterone. Progesterone has been
11 approved for use in pregnancy and is considered
12 Category B and has been shown to have no adverse
13 outcomes for use in pregnancy. In fact, is widely
14 used to prevent repetitive miscarriages and preterm
15 labor. So the medication does have approval for
16 use. There is not a problem with off-label use.

17 Have I answered your question?

18 MR. CHAIRMAN: Representative Clemmons,
19 you are recognized.

20 REPRESENTATIVE CLEMMONS: Thank you, Mr.
21 Speaker.

22 I'm not sure you have. So what I'm
23 getting at here is we're asking trained medical
24 professionals to give patients advice about
25 something or recommend something or a process or

1 give women false hope, perhaps, about a process
2 that may or may not work, and I don't hear you
3 saying that there is an overwhelming amount of peer
4 review study on the success rate of this process.

5 You discussed a 66 percent approval
6 rate of a very small pool. That gives me pause
7 when we are mandating creating a Class E felony for
8 doctors who don't do this. But a medical
9 professional -- why would they ever give a patient
10 who is in an emotionally fragile state false hope
11 about something when the success rate is, A, so low
12 and, B, not substantively tested or thoroughly.

13 In your 20-plus years of practicing
14 medicine, how often have you given a patient advice
15 or a recommendation based on a test that was six
16 people deep with a two-thirds success rate?

17 MR. CHAIRMAN: Dr. Boles, you're
18 recognized.

19 DR. BOLES: You're forgetting the study
20 that I quoted that has 754 patients still with a
21 68 percent success rate. That's almost three out of
22 four. Where if they don't get treatment, their rate
23 is pretty close to zero. Because without -- if you
24 take the mifepristone but do not take progesterone,
25 even if you don't take the Cytotec, the fetal

1 survival rate is as low as 8 percent. And that's a
2 report not from me or a pro-life physician. That's
3 a report of analysis of the data that was published
4 by Dr. Daniel Grossman who is an abortion provider.

5 And he wrote in a study that review of
6 the data shows that when a patient takes
7 mifepristone, the fetal survival rate can be as low
8 as 8 percent. Our study of 754 patients published
9 in a peer review journal shows that the current
10 regimen that we recommend has a 66 to 68 percent
11 success rate. So I don't believe you can call it
12 false hope to increase the fetal survival from
13 8 percent to 68 percent.

14 And I don't believe that when a patient
15 changes their mind and you refuse to respect their
16 choice -- because that's what the abortion
17 providers tell us. This issue is all about, I
18 think, the patient's choice. If the patient
19 chooses to change her mind and is asked
20 specifically by a patient -- and is asked -- the
21 patient specifically asks the abortion provider if
22 anything can be done and they're told "no," then I
23 don't believe that is ethical.

24 MR. CHAIRMAN: Representative Clemmons,
25 you are recognized.

1 REPRESENTATIVE CLEMMONS: Thank you,
2 Mr. Speaker.

3 And, you know, you just told my
4 colleague over here that doctors can currently do
5 this. So you saying that we're refusing to respect
6 a patient's choice, I don't know if that's
7 occurring right now if you say it's already allowed
8 to take place.

9 And my final question is do you intend
10 to perform any abortions in the future?

11 MR. CHAIRMAN: Dr. Boles.

12 DR. BOLES: No, I do not.

13 MR. CHAIRMAN: Representative Clemmons.

14 REPRESENTATIVE CLEMMONS: So you will
15 never be doing what you're asking other doctors to
16 do today?

17 DR. BOLES: I'm not asking any doctor to
18 perform an abortion. I'm asking that the abortion
19 providers be required to answer the question
20 truthfully when a patient looks at them and says,
21 "I'm sorry that I took this. I want to change my
22 mind." I have delivered babies who have been
23 successfully reversed. I currently have two
24 patients that I'm following that I started on the
25 reversal protocol within the last three weeks.

1 I spoke to some of those patients
2 yesterday in preparation for this hearing today. I
3 told them that I would be coming here to testify
4 and I asked them -- I said, "Would you be in
5 support of a law that would require the abortion
6 provider to inform you at the time you take the
7 Mifeprex that, if you change your mind, there's a
8 way to reverse it?" They all said, "Yes."

9 Patients who have been through this
10 process support this kind of legislation because
11 the other universal thing that I know in asking
12 every patient that the hotline has referred to me
13 that I ask them, "Did you ask your abortion
14 provider if there was a possibility of reversing
15 this?" And every single patient who asks that
16 question was told "no." Some of them were, in
17 fact, told that, if they didn't complete the
18 process, their baby would have birth defects and
19 that's dishonest because the FDA in it's pursual of
20 the approval for Danco's application asked Danco
21 "Are there any birth defects in the babies that
22 survive this process?" And Danco said "no."

23 REPRESENTATIVE CLEMMONS: And Danco --

24 MR. CHAIRMAN: Representative Clemmons,
25 you are recognized.

1 REPRESENTATIVE CLEMMONS: And who is
2 Danco again?

3 DR. BOLES: Danco is the pharmaceutical
4 company that produces Mifeprex.

5 REPRESENTATIVE CLEMMONS: That's
6 (indiscernible, simultaneous crosstalk) off the
7 medication?

8 DR. BOLES: I'm sorry?

9 REPRESENTATIVE CLEMMONS: No further
10 questions.

11 MR. CHAIRMAN: Okay.

12 Representative Byrd, you are
13 recognized.

14 REPRESENTATIVE BYRD: Thank you,
15 Mr. Chairman.

16 Is there any research that has been
17 done that shows what percent of women, if they had
18 known about this reversal process, would have not
19 followed through with abortion?

20 DR. BOLES: Could you repeat that?

21 REPRESENTATIVE BYRD: Yeah. Is there
22 any research that has shown what percentage of
23 women, if they had known about this reversal
24 process, would have not followed through with the
25 abortion?

1 MR. CHAIRMAN: Dr. Boles, you are
2 recognized.

3 DR. BOLES: I'm not sure that I can
4 answer that. There's not information that gives us
5 a specific percentage of the number of women who
6 regret what they have done after they take the pill.
7 What I have learned in talking to many of these
8 patients over the three or four years that I have
9 been part of the Abortion Pill Reversal network is
10 that there are women who do take the pill and
11 immediately regret it.

12 In fact, one that I talked to less than
13 two weeks ago was -- had found the hotline on an
14 internet search and was calling it begging for help
15 less than an hour after taking the first pill in
16 the series.

17 So can I tell you what the percentage
18 of women who take medication abortion pills then
19 regret it? No. I can't tell you that. Can I tell
20 you that there are a decent number of people that
21 do? Absolutely. The hotline gets at least a dozen
22 phone calls a day and on busier days of the week
23 sometimes considerably more than that. So there
24 are patients who seek this out and they find it not
25 because they are informed of it at their abortion

1 provider but because they find it themselves.

2 So we have no way of knowing how many
3 people didn't find this method and simply completed
4 the abortion process even though they regretted it.
5 There's no way to know that information.

6 MR. CHAIRMAN: Representative Byrd, you
7 are recognized.

8 REPRESENTATIVE BYRD: No further
9 questions.

10 MR. CHAIRMAN: Okay.
11 Chairman [sic] White, you are
12 recognized.

13 REPRESENTATIVE WHITE: Thank you,
14 Chairman.

15 Just for clarity on my part. What is
16 the time period between administration of the
17 mifepristone and the Cytotec if you're going
18 through the complete process?

19 DR. BOLES: 24 to 48 hours.

20 REPRESENTATIVE WHITE: 24 to 48 hours.

21 And I think you said this three times,
22 but I just want to make sure I understood
23 correctly.

24 If a dose of mifepristone is
25 administered, it can be reversed with a regimen of

1 progesterone. But without the progesterone, then
2 it can be harmful to the woman unless she completes
3 the Cytotec?

4 DR. BOLES: Yes. So the woman who
5 changes her mind after taking the mifepristone and
6 decides that she's not going to take the Cytotec and
7 hope for the best because she doesn't know there's a
8 better option, she is at risk. So when the patients
9 leave the abortion clinic and don't know that there
10 is an option to reverse and they simply think they
11 can figure out what to do on their own, those are
12 the women who are in danger.

13 REPRESENTATIVE WHITE: Thank you.

14 MR. CHAIRMAN: Representative Sherrell,
15 you are recognized.

16 REPRESENTATIVE SHERRELL: Thank you,
17 Chairman.

18 Thank you, Dr. Boles for being here
19 today.

20 And my question is I believe you said
21 you never have performed any abortions?

22 DR. BOLES: Correct.

23 REPRESENTATIVE SHERRELL: I just want to
24 say you're my kind of doctor, and I appreciate what
25 you stand for and appreciate you being here today,

1 and I appreciate you protecting life inside the
2 mother's womb. Thank you for being here today.

3 DR. BOLES: Thank you, sir.

4 MR. CHAIRMAN: Representative Dixie, you
5 are recognized.

6 REPRESENTATIVE DIXIE: You referenced
7 two different studies. The one with 754 and the one
8 with 6 or 12. Was the 700- -- the study with the
9 754, was it conducted under the same conditions as
10 the one with 12? Are we comparing apples to apples
11 here or are they two different studies with two
12 different scopes?

13 MR. CHAIRMAN: Dr. Boles, you are
14 recognized.

15 DR. BOLES: They are two different
16 studies conducted by two different people with two
17 different purposes. The first study that I
18 referenced released in 2012 only had six patients
19 and it was not a case controlled-type study. It
20 simply reported a series of six patients in whom
21 reversal was attempted and in whom four of the six
22 were successful.

23 There were two other small studies that
24 were published, which I don't have with me today.
25 And then there was a final study by the creators of

1 the reversal regimen that you do have in the folder
2 that I gave you published by Dr. George Delgado in
3 a peer review journal in which he evaluated 754
4 patients that wished to reverse the effects of the
5 mifepristone. They did not take their Cytotec and
6 they took progesterone in a variety of different
7 regimens. They were randomized to receiving an
8 injection versus an oral regimen and there were
9 different oral regimens that were used.

10 This study of nearly a thousand
11 patients did show that the most effective regimen
12 is now the one we currently recommend and that it
13 has a 68 percent success rate with no increase in
14 birth defects and no increase in adverse outcomes
15 for the woman.

16 The final study you've asked about was
17 conducted by an abortion doctor who randomized 12
18 women that sought an abortion into two groups of
19 six each. Some received the abortion pill only and
20 placebo; some received the abortion pill and the
21 reversal regimen that we currently recommend.
22 Those were the studies that I've referenced.

23 MR. CHAIRMAN: Representative Dixie, any
24 further question?

25 REPRESENTATIVE DIXIE: (No audible

1 response.)

2 MR. CHAIRMAN: Okay. Thank you.

3 Chairman Smith, you are recognized.

4 REPRESENTATIVE SMITH: Thank you, Dr.
5 Boles.

6 Just as clarification, if this were
7 taken out of the scope of treating abortion, would
8 this be viewed as just simply informed consent,
9 talking with a patient about the options that they
10 have as a standard approach to care if it were
11 removed from the abortion issue? Because I know
12 that's what is so controversial in the minds of
13 many. But if you remove this practice of informing
14 and giving full information to the patient in any
15 other scope of care, would this just be considered
16 informed consent in a standard practice of care?

17 DR. BOLES: Absolutely. That's -- that
18 is one of my points.

19 REPRESENTATIVE SMITH: Thank you, Dr.
20 Boles.

21 DR. BOLES: For example, if a patient
22 comes to me and she wants to have her tubes tied, my
23 informed consent process with her is similar to what
24 should occur with the informed consent process for
25 the abortion pill. I say to her, "Are you sure you

1 don't want anymore children because you have to
2 consider this method of birth control to be
3 irreversible."

4 And then I go on to tell her, "You have
5 probably heard of people having their tubes put
6 back together. That is possible but it only works
7 about 50 percent of the time and you can't use this
8 as your method of birth control if you're going to
9 think about doing that in the future. That would
10 not be a good choice." That's my informed consent
11 process before tying a woman's tubes.

12 In a similar fashion, basic ethical
13 requirements for informed consent on taking an
14 abortion pill should say that if you take this and
15 regret it afterwards, there is a way to try to
16 reverse it. It won't always work, but you can try
17 it and here is how you access that information.
18 That process can be completed, as I just stated in
19 less than 15 seconds and in no way is an undue
20 burden on either the woman or the abortion
21 provider. It's simply medical ethics.

22 MR. CHAIRMAN: Chairman Smith, you are
23 recognized.

24 REPRESENTATIVE SMITH: Thank you,
25 Doctor, and thank you Mr. Chairman for sponsoring

1 this bill. This is good standard of practice and
2 good standard of care, and I think this is an easy
3 vote for this member. Thank you.

4 Thank you.

5 MR. CHAIRMAN: Thank you.

6 Representative Miller, you are
7 recognized.

8 REPRESENTATIVE MILLER: Thank you,
9 Mr. Chair.

10 Mr. Chairman, I think last week in
11 subcommittee we heard from a female physician.
12 Will we hear from her while we are out of session?

13 MR. CHAIRMAN: Thank you. She was
14 supposed to be on the schedule for today. She was
15 on the schedule for last week. And I do not see her
16 in the audience, and I do not know that we have
17 anyone on the other -- that may want to testify
18 while we are out of session.

19 REPRESENTATIVE MILLER: Thank you,
20 Mr. Chairman.

21 Doctor, thank you for your
22 presentation.

23 Do you support a woman's right to
24 choose to have an abortion or not have an abortion?

25 DR. BOLES: I support the woman's right

1 to access birth control and to make the decisions
2 about whether or not to become pregnant. But once
3 another life is involved -- because science and
4 ethics are very clear that human life begins at
5 conception -- once another life is involved, I do
6 not support abortion as a human right in any case
7 other than to save the life of the mother, which is
8 an extremely rare occurrence.

9 MR. CHAIRMAN: Representative Miller,
10 you are recognized.

11 REPRESENTATIVE MILLER: However, you
12 support the right of the woman to change her mind in
13 a case of reversal? You support her right to choose
14 to change her mind?

15 DR. BOLES: When she is making the
16 choice to save the life of a child that she thought
17 a moment before that she didn't want then, yes, I
18 support that. Because that choice potentially saves
19 a life. The choice to abort the pregnancy always
20 ends a life. There's a vast difference between
21 those two positions.

22 MR. CHAIRMAN: Representatives Miller?

23 REPRESENTATIVE MILLER: Thank you,
24 Mr. Chairman. Thank you.

25 MR. CHAIRMAN: Thank you.

1 Representative Cooper, you are
2 recognized.

3 REPRESENTATIVE COOPER: Thank you
4 Mr. Chairman.

5 I apologize, everyone. I had to run
6 out to present a bill in another committee and
7 that's why I was not here and I missed part of your
8 presentation.

9 I want to know -- this pill that is
10 allowed right now it does destroy -- prevents a
11 baby from being born. In other words, it kills the
12 embryo.

13 DR. BOLES: Yes, it does.

14 REPRESENTATIVE COOPER: And I know there
15 may be a lot of studies because, like I said, I
16 missed part of your presentation.

17 If it kills the baby, what does it do
18 to the mother?

19 DR. BOLES: The application that Danco
20 Pharmaceuticals made to the Food and Drug
21 Administration would lead you to believe that there
22 are very few side effects or adverse outcomes for
23 the mother. However, there have been women who as a
24 result of unusual infections after the use of this
25 medication, and there are many women who have had

1 bleeding that require transfusion or surgery
2 afterwards.

3 And, you see, the problem here is that
4 while 29 states require that the complications of
5 abortions be reported to the State's Department of
6 Health or to the Center for Disease Control, 21
7 states don't require reporting at all. And of the
8 29 who do, the enforcement mechanisms in those
9 states have no teeth. So we don't have accurate
10 information on how often women experience bad
11 complications from use of this abortion regimen.

12 There are a number of reports to the
13 Food and Drug Administration of adverse events.
14 But the vast majority of these adverse outcomes and
15 complications were not reported by abortion
16 providers. They were reported by emergency room
17 doctors and private OB/GYNs like myself to the
18 adverse event reporting database. That data with
19 several thousand adverse outcomes is currently
20 being analyzed by a group of which I am a part and
21 we expect publication to occur later this year on a
22 more accurate incidence of adverse outcomes using
23 the medication abortion regimen.

24 So in answer to your question, yes,
25 there are the potential for bad outcomes for women

1 who use this medication.

2 REPRESENTATIVE COOPER: Okay. Earlier
3 you said --

4 MR. CHAIRMAN: Representative Cooper,
5 you are recognized.

6 REPRESENTATIVE COOPER: Do you mean that
7 mothers have lost their lives?

8 DR. BOLES: Some mothers have. A few
9 mothers have lost their lives. Most of those deaths
10 have occurred because of atypical infections that
11 typically are only seen after the use of medication
12 abortion. But there -- there's the potential as
13 well for death from blood loss or other problems.

14 REPRESENTATIVE COOPER: One moment, Mr.
15 Chair, and I'll be finished.

16 And with that few, do you have a
17 number?

18 DR. BOLES: I do not have a number.
19 That's what we're working on. The group that I'm a
20 part of is working on a number.

21 REPRESENTATIVE COOPER: Thank you,
22 Mr. Chair and thank you for being here.

23 MR. CHAIRMAN: Thank you.

24 I have one clarification on something
25 that you answered for her. She had asked if the

1 first pill, mifepristone, damaged the baby -- I
2 think is what she said. I think -- would it be
3 more clear to say that that pill creates an
4 environment that's not conducive to the baby
5 therefore that damages the baby as opposed to
6 specifically it damaging the baby?

7 DR. BOLES: The pill -- the intended
8 effect of the pill is to kill the child, and it
9 accomplishes this by interfering with the action of
10 progesterone. That action reduces the blood supply
11 into the uterus which causes the placental tissue to
12 become unstable and it deprives the placenta and the
13 embryo or fetus of oxygen and other critical
14 nutrients. That's the -- if you want to call it,
15 embryocidal or fetocidal. That's the fetocidal
16 effect.

17 MR. CHAIRMAN: Thank you.

18 Representative Dixie, you have another
19 question?

20 REPRESENTATIVE DIXIE: Yes.

21 Are you familiar with the report that
22 was produced by the Louisiana Department of Health
23 which did a study based on the effects of abortions
24 induced with drugs and chemicals if they can be
25 reversed and to report the findings to their state

1 and house committees?

2 Are you familiar with that?

3 DR. BOLES: I was not aware that
4 Louisiana had undertaken that.

5 REPRESENTATIVE DIXIE: Okay. Well,
6 after that study they have several experts -- seven,
7 I think, to be exact -- you know, from medical
8 fields, OB/GYN, pharmacies -- they had an array of
9 panels.

10 And the conclusion was that there was
11 neither sufficient evidence or a scientific basis
12 to conclude that the abortion induced with drugs or
13 chemicals can be reversed. So I think what you're
14 asking -- to go along with what Representative
15 Clemmons was saying -- we're asking to set a
16 standard on something that cannot be proven that's
17 not safe. And even if you do 754 people at 68
18 percent of that, I don't think that's
19 representative to be asking people to -- for us to
20 mandate something that's not proven or recommend
21 something that's not proven.

22 MR. CHAIRMAN: Dr. Boles, you are
23 recognized.

24 DR. BOLES: To specifically answer that,
25 I would have to see how the Louisiana Department of

1 Health arrived at their conclusions because I
2 would -- with what you have stated about their
3 conclusions, I would vigorously disagree.

4 You know, the abortion industry -- you
5 keep focusing on 754 patients not being enough.
6 But the abortion industry and Dr. Creinin want us
7 to conclude that this is not safe based on a series
8 of 12 patients. Which is it?

9 MR. CHAIRMAN: Representative Dixie, you
10 are recognized.

11 REPRESENTATIVE DIXIE: I don't want to
12 get confused or lost in confusion. But I just want
13 to make it clear that I believe that the one that
14 was based on the six patients was stopped because of
15 the risk of the health for women. The one at 754,
16 I'm not sure -- I don't think that there's enough
17 information out there to be making this -- to make
18 this a mandate. That is my question.

19 If one was stopped due to concerns of
20 health of women in this particular trial, I think
21 that there's something that maybe we should take
22 some time to even -- maybe we should look at to get
23 the members to look at the report that the
24 Louisiana Department of Health put forth so we can
25 be a little bit more informed before we make this

1 decision.

2 DR. BOLES: In response to that, again,
3 the study was stopped because two of the six women
4 in the group who only took the abortion pill had a
5 bad outcome. The six women in the group that took
6 the progesterone to reverse it did not have bad
7 outcomes. Five of the six had surviving embryos and
8 none of the six required a blood transfusion or a
9 surgery. The only two adverse outcomes were in the
10 group that took the abortion pill without the
11 reversal regimen and one of them required surgery
12 and the other one required surgery and a blood
13 transfusion.

14 So if we want to draw a conclusion from
15 a series of 12 patients that was stopped, it was
16 stopped because the ones that didn't get the
17 reversal regimen did not do well. That's the real
18 conclusion that you can draw from that study. And
19 from a study of 754 patients that show no increase
20 in bad outcomes for the women who try reversal and
21 show a 68 percent success rate at saving the baby's
22 lives, I think that speaks for itself.

23 MR. CHAIRMAN: All right. Thank you. I
24 think we got one last -- Chairman [sic] Kumar and
25 then we are going -- I think everybody has had their

1 questions and we are going to wrap this up.

2 But, Chairman Kumar, you are
3 recognized.

4 REPRESENTATIVE KUMAR: Thank you,
5 Mr. Chairman. Thank you for your generosity.

6 Dr. Boles, thank you for being here.

7 DR. BOLES: You're welcome.

8 REPRESENTATIVE KUMAR: I think stopping
9 the study is required as a humane gesture or the
10 responsibility to our patients when the outcomes are
11 so clear. And that's not an uncommon phenomenon, is
12 it?

13 DR. BOLES: That's correct.

14 REPRESENTATIVE KUMAR: Providing a
15 patient with full information is part of the
16 informed consent. You know, medication you're
17 taking, can it be the worst, what side effects does
18 it have? That should be a part of the informed
19 consent. And it's very good that we are -- we have
20 legislation to this regard so this process does not
21 get overlooked. But certainly, this should really,
22 in a way, should not be necessary if we were all to
23 inform the patients completely of the effects of
24 what treatment we are giving them and the
25 possibilities of reversal.

1 These are remorseful and intense in
2 overwhelming times, and these are patients, in my
3 opinion that certainly need complete information
4 and reassurance that it's an uncertain territorial
5 acting and certainly the situation can be rescued
6 if need be, if they change their mind.

7 My last question to you is is there
8 knowledge within the studies and science at this
9 time about babies that were delivered following the
10 reversal process? How old are they now and are
11 there any health consequences to them?

12 MR. CHAIRMAN: Dr. Boles, you are
13 recognized.

14 DR. BOLES: The first one would have
15 been delivered in 2007 or 2008, so we now have a
16 teenager that was successfully reversed. And since
17 then, there are over a thousand reported deliveries
18 and then there are some women who did not follow up.
19 Of the ones that we have been able to follow, of the
20 ones that have been -- that it's been possible to
21 track, there is no increase in the number of
22 problems that the child has from the standpoint of
23 birth defects or developmental issues or behavioral
24 issues. None.

25 ///

1 In fact, the statistic I mentioned
2 earlier gives -- shows another benefit to using
3 this and perhaps that will someday be broadened to
4 all pregnancies. But when you have the preterm
5 delivery rate being around 10 percent with
6 premature delivery being responsible for an
7 enormous number of health care problems and the
8 expenditure of an enormous amount of health care
9 dollars, this regimen appears to reduce the preterm
10 delivery rate from 10 percent down to less than
11 3 percent.

12 So there have been no adverse outcomes
13 for the babies noted either development or behavior
14 or birth defects. And there is -- there are two
15 very significant benefits that have been shown.
16 One, saving the baby's life 68 percent of the time.
17 And, two, reducing the preterm delivery rate.

18 REPRESENTATIVE KUMAR: Thank you, Dr.
19 Boles. We are grateful for your presence and your
20 knowledge. Thank you.

21 DR. BOLES: Thank you.

22 MR. CHAIRMAN: All right. Thank you. I
23 appreciate your testimony.

24 And seeing no further questions, we
25 will go back into session.

1 We are back on the amendment. We have
2 a -- the question has been called on the amendment
3 without objection. We are voting on Amendment
4 014982.

5 All those in favor say "aye."

6 COMMITTEE MEMBERS: (Collectively) Aye.

7 MR. CHAIRMAN: Opposed?

8 COMMITTEE MEMBERS: (No audible
9 response.)

10 MR. CHAIRMAN: Ayes have it. The
11 amendment goes on the bill.

12 I believe we have a second amendment by
13 Representative Dixie.

14 Do you plan to run that amendment?

15 REPRESENTATIVE DIXIE: If I can explain
16 it.

17 MR. CHAIRMAN: Okay. It is Amendment
18 015380.

19 UNIDENTIFIED SPEAKER: Motion on
20 amendment.

21 UNIDENTIFIED SPEAKER: Second.

22 MR. CHAIRMAN: Okay. You have a motion
23 and a second.

24 REPRESENTATIVE DIXIE: So with the
25 previous amendment, I think there's some signage --

1 well, with this bill there's going to be some
2 signage that's going to be in waiting rooms or in
3 the physician area. So this will just require some
4 additional language to put a warning to patients
5 that there have been no medical trials completed
6 that prove a medication abortion can be reversed.
7 And that's simply what my amendment does -- add
8 verbiage.

9 MR. CHAIRMAN: Okay. Chairman Hill,
10 you're recognized on the amendment.

11 CHAIRMAN HILL: Thank you very much.

12 In light of the fact that we just spent
13 50 minutes to the contrary of what this amendment
14 says, I move to table Amendment Number 2.

15 UNIDENTIFIED SPEAKER: Second.

16 MR. CHAIRMAN: Okay. Proper motion.

17 With that, we will be voting on the
18 tabling motion.

19 All those in favor of tabling Amendment
20 015380 say "aye."

21 COMMITTEE MEMBERS: (No audible
22 response.)

23 MR. CHAIRMAN: Debate is off all except
24 for the sponsor before we go to the tabling motion.

25 REPRESENTATIVE DIXIE: We did talk about

1 the clinical trials, but there is nothing that has
2 been successfully proven that this is very effective
3 for women in these trials. I think that it's not
4 sufficient enough, and I think that this verbiage is
5 very important to go on the signage as well.

6 And with that, that's all I have to say
7 on this and thank you, Mr. Chairman, for giving me
8 a second to speak about this.

9 MR. CHAIRMAN: Thank you. With that, we
10 will be voting on the tabling motion.

11 All those -- we are tabling 015380.
12 All those in favor of tabling the amendment, vote
13 "aye."

14 COMMITTEE MEMBERS: (Collectively) Aye.

15 MR. CHAIRMAN: Opposed?

16 COMMITTEE MEMBERS: (Collectively) No.

17 MR. CHAIRMAN: Ayes have it. We have
18 tabled the amendment.

19 We are back on House Bill 2568 as
20 amended.

21 Chairman Faison, you are recognized.

22 REPRESENTATIVE FAISON: I renew my
23 motion.

24 MR. CHAIRMAN: Chairman White, you are
25 recognized.

1 REPRESENTATIVE WHITE: Thank you,
2 Chairman.

3 Just one more time, based on the
4 question I asked our guest, would you just restate
5 what the signage says in the original bill in the
6 amendment that we just passed?

7 REPRESENTATIVE FAISON: Thank you,
8 Chairman White.

9 This bill would provide -- or require
10 abortion facilities to post both signage in the
11 facilities as well as give verbal information to
12 women about the procedure as well as how and where
13 they can procure the abortion pill reversal if they
14 so choose.

15 MR. CHAIRMAN: Thank you.
16 Representative Clemmons, you are recognized.

17 REPRESENTATIVE CLEMMONS: Thank you,
18 Mr. Chairman, and thank you sponsor.

19 I appreciate what I believe is your
20 intent with this legislation. I did raise the
21 issue earlier of false hope. And I have a sincere
22 concern about that, and I know that your intent
23 with this legislation is not to increase the number
24 of women who come in thinking that if they change
25 their mind they can just reverse that. I think

1 that could be an effect to this legislation that
2 may not be considered for, you know, this body has
3 spent during my tenure a lot of time limiting the
4 constitutional rights of women. And this bill
5 seems to do the reverse of that or could have the
6 effect of doing the reverse of that.

7 And I'm reading this notice that's to
8 be posted in the doctors' offices, and I think the
9 language of it is very telling because we've talked
10 a lot about the medical studies or lack thereof and
11 sample sizes. And I just want to read this.

12 "Recent developing research has
13 indicated that mifepristone alone is not always
14 effective in ending a pregnancy. It may be
15 possible to avoid." There seems -- there's a lot
16 of iffy language in this notice.

17 And this is a pretty thoroughly drafted
18 piece of legislation. You've got down to the font
19 of what it has to say on the website and so forth.

20 Are you concerned, given what we've
21 heard today, the testimony I think you heard in the
22 subcommittee from both sides and just the language
23 of this legislation that you are providing women
24 who are already in an emotional state making
25 probably, I would argue, the most difficult

1 decision in their life. Are you concerned you're
2 giving them false hope?

3 MR. CHAIRMAN: Chairman Faison, you are
4 recognized.

5 REPRESENTATIVE FAISON: Thank you, Mr.
6 Chairman.

7 The gentleman from Shelby County -- I
8 mean from Davidson County, I will remind you that
9 two years ago in Washington D.C. in a very
10 bipartisanship manner, every democrat and
11 republican alike in the House and the Senate, which
12 is an extreme rarity, they voted for a law called
13 Right to Try. And that would give Americans the
14 ability to enter in and try some medical treatment
15 that may or may not work. It could possibly give
16 them false hope, but it could also possibly give
17 them hope. I would encourage you that this is not
18 what we're doing here.

19 This is not 100 percent. Very few
20 things in medicine are 100 percent. But there are
21 times that a young lady -- and I have actually
22 spoken with some -- that they were devastated by
23 what they did, they got scared, they got pressured,
24 by people -- maybe pressured by a perpetrator, and
25 they realized, "You know what, I need a chance. I,

1 at least, can try to undo this."

2 And I'm also intrigued that someone
3 such as yourself who is a champion -- so-called
4 champion for women's right to choose, would want to
5 deny them the ability to understand that this is a
6 choice that they can make. This is another choice
7 to provide for them.

8 So I'm not challenged at all that this
9 isn't 100 percent. I'm encouraged that there is a
10 possibility and that this could save a life and
11 that we're giving a mom another choice.

12 MR. CHAIRMAN: Represent Clemmons.

13 REPRESENTATIVE CLEMMONS: Thank you, Mr.
14 Chairman.

15 And thank you for that response. I
16 guess my concern is to address your last point.
17 Nothing in the law prohibits this from taking place
18 right now. I think it's up to the medical
19 professional's discretion. And right now we are
20 adding something into the standard of care or
21 seeking to -- it appears to add something into the
22 standard of care of medical professionals who, you
23 know, they are not prevented from doing this
24 already.

25 So I don't think that we are standing

1 in the way or that the law prohibits this or stands
2 in the way in any respect. And, you know -- and I
3 get that there's two sides to this issue, and I
4 certainly never heard from a woman who has been
5 denied that opportunity. You very well may have as
6 you said.

7 The other issue I want to address here
8 is we are creating a Class E felony in civil
9 liability even with the award of attorney's fees in
10 this legislation. I assume that's your attempt to
11 put some teeth into this and force medical
12 professionals to comply with it. But, you know,
13 this body has decimated medical malpractice in the
14 State of Tennessee.

15 And so really the teeth you're seeking
16 to put into it, because of our medical malpractice
17 laws and tort reform, the teeth that I think you're
18 intending to put into this law is virtually
19 nonexistent because of the high hurdles that we
20 have in the State of Tennessee in that respect.

21 So I just point that out to you, and I
22 don't know that a response is necessary. But thank
23 you very much, and I appreciate your time,
24 Mr. Chairman.

25 MR. CHAIRMAN: Thank you. Any further

1 questions?

2 Seeing none, we are voting on House
3 Bill 2568.

4 All those in favor, say "aye."

5 COMMITTEE MEMBERS: (Collectively) Aye.

6 MR. CHAIRMAN: Ayes have it. The bill
7 moves on to Calendar and Rules.

8 If you wish to be recorded as a "no"
9 please -- or have your vote recorded, please tell
10 the clerk.

11 (WHEREUPON, the foregoing proceedings
12 were concluded.)

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